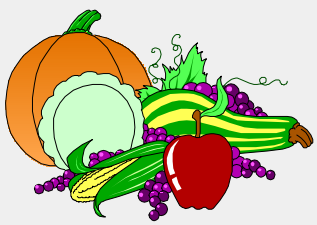
PEC UPDATE

VOLUME 97-02 **15 NOVEMBER 1996**

DOD PharmacoEconomic Center, 2107 17th Street, Bldg 4197, Ft Sam Houston, TX 78234-5036
DSN: 471-4311; Commercial: (210) 221-4311: FAX Extension: 4314
E-Mail: hscphaec@smtplink.hcssa.amedd.army.mil HomePage: http://www.ha.osd.mil/hppec2.html#Start

ISSUE HIGHLIGHTS

Happy Thanksgiving!



FDA-Approved Drugs for Unlabeled Indications

The PEC recently adopted a policy recognizing the use of Food and Drug Administration (FDA) approved drugs for unlabeled indications, when appropriate.[1] Physicians have always been free to prescribe an FDA-approved drug for unlabeled indications based on clinical judgment in the context of the prevailing standards of care. It is estimated that some 40% to 60% of all prescriptions are for uses the FDA has not approved.[2]

In the analysis of any given disease state, the PEC must consider all relevant drug treatment options to determine the most cost-effective treatment strategies. Many drugs have sufficient scientific evidence to support their use in a given disease state, and their use is well recognized and accepted by physicians, even though the drugs may not have an FDA approval for that particular disease state. For example, N-acetylcysteine was the treatment of choice, indeed the only treatment, for acetaminophen overdose for many years before it carried an FDA indication. Other examples include aspirin for post-myocardial infarction prophylaxis and alpha-adrenergic blockers, like prazosin, for benign prostatic hyperplasia.

For these reasons, the PEC will endorse the use of FDA-approved drugs for unlabeled indications where appropriate. Additionally, such drugs will be included in disease state analyses, which may result in their selection for the Tri-Service Formulary and promotion as preferred treatment for a given disease state.

Military medical treatment facility pharmacies will fill prescriptions for non-FDA-approved indications when these therapies are appropriate and proven effective for the treatment of disease, such as prazosin for benign prostatic hyperplasia or aspirin for post-myocardial infarction.[1]

1. Pharmacoeconomic Center notice regarding use of drugs for unlabeled applications. Federal Register. September 4, 1996;61:46632.
2. Associated Press. Unapproved use of drugs mulled. In: AP Online. FaxBack FaxNews 1996 Jan 16; Document no. 3564.

Correction: PEC Update 96-11

On page A6 of PEC Update 96-11 (16 August 1996), Figure 1 should be corrected to read, "Step 1: Intermittent Therapy, Short acting inhaled beta-agonist prn not more than **once a week over a 3 month period**."

From the Mailbag.....

PEC Q & A

Q: PEC Update 96-11 (16 August 1996) on the management of asthma mentions the asthma disease management program, AIR Keesler, in Appendix A. The program description indicated that home nebulizers are being directly issued to pediatric patients with moderate to severe asthma. How did Keesler get such a great deal on the nebulizers?

A: As part of the Asthma Is Reversible (AIR) Keesler program, the respiratory therapy section was asked to find a source of supply for home nebulizer compressors. The compressors were to be purchased with hospital funds, and distributed to patients with severe to moderate asthma through the pediatric clinic. Regional medical supply/equipment distributors were contacted. Several compressors were evaluated for quality/reputation, warranty, portability, and price. One nebulizer compressor was selected at a unit cost of $72.35, saving $100.89 from the CHAMPUS allowable cost of $173.24. Forty units were purchased for the pediatric clinic and are issued to patients on the recommendation of the staff pediatric pulmonologist. The goal of the program is to improve the patient's ability to manage their disease, leading to improved quality of life and reduced medical costs. Emergency room visits and hospital admissions are expected to be reduced.

AIR Keesler is tracking the impact of this program. For additional information, contact MSGT Donavan Knight, NCOIC Respiratory Therapy, Keesler AFB, at DSN 597-6062, COM (601) 377-6062, or FAX: DSN 597-8165, COM (601) 377-8165.

Q: The PEC Management of Asthma Guideline published in the PEC Update 96-11 (16 August 1996) noted the addition of a spacer device (InspirEase®) to the Tri-Service Formulary (TSF). What about peak expiratory flow (PEF) devices?

A: Peak expiratory flow devices were not selected for TSF addition for two primary reasons. First, the market research conducted on the expense of PEFs in DOD revealed a small market unlikely to be impacted by a TSF selection. For example, several large DOD medical treatment facilities (MTFs) spend < 0.02% of their operating funds per year on PEFs. Second, the PEC is chartered to consider pharmacoeconomic issues. A spacer device was added to the TSF because it is a drug delivery device that is necessary for proper drug administration.

However, PEFs are a critical adjunct in the management of asthma. The clinical consultant panel convened to review the asthma treatment model agreed there are many PEFs that work equally well. MTFs should be free to make their own decision based on input from their providers and according to their patient's needs.

There are many opportunities for savings at the local level. While one MTF may purchase the MiniWright PEF from the supply depot for $18.00-$20.00/unit, another MTF may purchase the Personal Best PEF for $3.10/unit. In an operating budget of $50-100 million, PEFs could account for $10,000-$20,000 per year at a large MTF. Shrewd local purchasing could reduce those costs to $1700-$3300 per year. As budgetary constraints become tighter and tighter, MTF commanders will be increasingly reliant on the

service members in the trenches to find savings, no matter how small, to make ends meet.

Q: Why were cromolyn solution for nebulization and cromolyn inhalers not included on the Tri-Service Formulary for management of asthma? We use this medication quite frequently at our facility.

A: In general, cromolyn is not a cost-effective controller medication when compared with the inhaled corticosteroids for Step 2 asthma therapy in both pediatric and adult patients. Cromolyn is the only controller medication available as a nebulization for very young children (< 2 years of age). While cromolyn nebulization is **not** cost-effective for a patient who can use other drugs and dosage forms, it may be the only controller medication for these young children. *Cromolyn was not selected for the TSF because of its overall lack of cost-effectiveness and its potential for overuse, at great expense to the MTF*. Facilities can add cromolyn to their local formulary as necessary for optimal patient care.

Q: Why was beclomethasone deleted from the TSF, particularly since it is the inhaled steroid of choice in pregnant asthmatic patients and has extensive data in children?

A: Beclomethasone was deleted because of its relative lack of cost-effectiveness compared with other inhaled corticosteroids. The asthma treatment analysis was focused on the majority of asthmatics with mild to moderate disease, and thus the TSF selections were made accordingly. However, in some subsets of the asthma popu-lation, such as pregnant patients, beclomethasone may be the appropriate treatment option. Military treatment facilities should supplement the TSF with any additional medications as necessary to meet its patients' needs.

In the Literature..... Recent Guidelines and Consensus Statements

International AIDS Society-USA
Carpenter CCJ, Fischl MA, Hammer SM, Hirsch MS, Jacobsen DM, Katzenstein DA, et al. Antiretroviral therapy for HIV infection in 1996: recommendations of an International Panel. *JAMA* 1996;276:146-54.

American College of Rheumatology
American College of Rheumatology Ad Hoc Committee on Clinical Guidelines. Guidelines for the management of rheumatoid arthritis. *Arthritis Rheum* 1996;39:713-22.

American College of Rheumatology Ad Hoc Committee on Clinical Guidelines. Guidelines for monitoring drug therapy in rheumatoid arthritis. *Arthritis Rheum* 1996;39:723-31.

American Thoracic Society
American Thoracic Society. Position statement: Ciga-rette smoking and health. *Am J Respir Crit Care Med* 1996;153:861-5.

1997 PEC Ambulatory Care Pharmacist Conference

The 1997 Ambulatory Care Pharmacist Conference is just around the corner! The conference will be held January 26-29, 1997 at the Hilton Palacio del Rio on the Riverwalk in San Antonio, Texas. Look for tentative program topics and additional details in your December PEC Update. For additional information, please call Eugene Moore, Pharm.D., at the PEC.

Welcome to New Staff Members

The PEC would like to welcome LTC(P) Dan Remund, COL Ernest Sutton, and SFC Thomas Bolinger to its staff.

LTC(P) Dan Remund recently concluded 3 years of study focused on pharmacoeconomics and

pharmacoepidemiology in the Graduate Program in Social & Administrative Pharmacy at the University of Minnesota. He will defend his Ph.D. dissertation in December 1996. LTC(P) Remund's previous assignments include Assistant Chief of Pharmacy at Fitzsimons Army Medical Center, Denver, Colorado, Chief of Pharmacy at Fort Leavenworth, Kansas and Augsburg, Germany, and pharmacy instructor at the U.S. Army Academy of Health Sciences. LTC(P) Remund will serve as a Deputy Director of the PEC and Director of the Uniformed Services Prescription Database Project.

COL Ernest L. Sutton has joined the PEC as the Army physician representative after completing his Fellowship in Health Care Policy at the Uniformed Services University of the Health Sciences (USUHS), Bethesda, MD. He is a Diplomate of the American Board of Internal Medicine and Gastroenterology, holds a MS in Pharmacology and a MPH in Health Services Administration, and is a graduate of the US Army War College. He has served as Command Surgeon for the US Southern Command (Panama), Hospital Commander in Würzburg, Germany, and Gastroenterology Teaching Chief at Letterman Army Medial Center.

SFC Thomas Bolinger joins the PEC staff as our new Non-Commissioned Officer In Charge (NCOIC). SFC Bolinger was previously assigned to Landstuhl Regional Medical Center where he served as NCOIC of the outpatient, inpatient, and support sections of the pharmacy. He also served as the point of contact for CHCS and was the purchasing agent for Landstuhl's Prime Vendor Contract.

PEC Bulletin Board

The Pharmacoeconomic Center (PEC) now has a bulletin board service to provide our readers yet another means to obtain PEC Updates, disease state reviews, treatment guidelines, drug utilization evaluations, and other announcements from the PEC. All documents can be downloaded from the bulletin board to be used by military medical treatment facilities in their local newsletters and educational materials.

The PEC has four telephone numbers dedicated to the Bulletin Board. These numbers are listed in the box below and can be accessed through com-mercial or DSN lines. If you experience any prob-lems connecting to the bulletin board, please contact SFC Thomas Bolinger at the PEC at (210) 221-4603 or DSN 471-4603.

PEC Bulletin Board Telephone Numbers

Prefix: COM (210) 221-		DSN 471-	
Line 1	-3371	Line 3	-3373
Line 2	-3372	Line 4	-3374

Pharmacoeconomic Center Staff Directory

Commercial: (210) 221- DSN: 471- FAX extension: -4314 E-mail: hscphaec@smtplink.hcssa.amedd.army.mil

Errol Moran, RPh, MS, COL, MS, USA	4211	Ernest Sutton, MD, MS, MPH, COL, MC, USA	4217
Mary Weber, RPh, MS, BCPS, FASHP, LCDR, MSC, USN	5494	C. Stewart Reeves, MD, CAPT, MC, USNR	5596
Greg Russie, RPh, MS, MAJ, BSC, USAF	4514	Rick Downs, MD, FACP, LTC, MC, USAF	916-7498*
Dan Remund, RPh, MS, LTC(P), MS, USA	5407	Mel Miller, RPh	4513
Andrea Ries, PharmD, BCPS	4606	Eugene Moore, PharmD.	5694
Thomas Bolinger, SFC, USA	4603	Eddie Bermudez, SSG, USA	4603
Carol Scott	4311		*DSN: 429-